

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK**

STEUBEN FOODS, INC.,

Plaintiff,

v.

OYSTAR GROUP ET AL.,

Defendants.

**REPORT AND
RECOMMENDATION**

1:10-cv-00780-EAW-JJM

1:12-cv-00904-EAW-JJM

1:13-cv-00892-EAW-JJM

1:13-cv-01118-EAW-JJM

Familiarity with the background of these patent infringement actions (and with the court's abbreviation of party names) is presumed. Continues the claim construction process, this Report and Recommendation focuses on the following claim language of U.S. Patent No. 6,945,013 (the “‘013 Patent”):¹ “a feedback control system for maintaining aseptic bottling conditions” (Claim 9); “disinfecting the bottles . . . with hot hydrogen peroxide spray” (Claim 20); and “a residual level of hydrogen peroxide . . . less than 0.5 PPM” (Claim 20). A Markman hearing (Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996)) concerning this claim language was held on June 16, 2020 [386], followed by post-hearing submissions [387-89, 391, 393].

A. “A Feedback Control System for Maintaining Aseptic Bottling Conditions”.

Claim 9 of the’013 patent contains the phrase “a feedback control system for maintaining aseptic bottling conditions”. The Oystar defendants argue that this phrase is a

¹ [1], pp. 10-32 (CM/ECF pagination). Unless otherwise indicated, bracketed references are to CM/ECF docket entries in 10-cv-780, and page references are to the documents themselves rather than to CM/ECF pagination. Many of the documents referred to in this opinion have been filed in all of the Steuben cases, under different docket numbers.

“means-plus-function” claim subject to 35 U.S.C. §112, ¶6,² and that it is indefinite for failing to adequately identify a structure corresponding to the function described in the claim. Oystar letter brief [387], pp. 9-10. Steuben counters that “there is a presumption under the law that this claim term, which does not recite ‘means for’, is not a means-plus-function claim term”. Steuben’s Letter Brief [388], pp. 11-12, *citing Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1349 (Fed. Cir. 2015).

In Williamson the Federal Circuit, sitting *en banc*, acknowledged that “the failure to use the word ‘means’ . . . creates a rebuttable presumption . . . that §112, para. 6 does not apply”. However, the court “expressly overrule[d] the characterization of that presumption as ‘strong’” (*id.* at 1349), holding that even “when a claim term lacks the word ‘means,’ . . . §112, para. 6 will apply if the challenger demonstrates that the claim term fails to recite sufficiently definite structure or else recites function without reciting sufficient structure for performing that function.” *Id.* at 1348.

Steuben urges me to adopt the reasoning of District Judge Colm F. Connolly in the Steuben/Shibuya case, which was transferred from this district to the District of Delaware last year (10-781 [482]). Among the claim terms which Judge Connolly addressed in an August 20, 2020 Markman hearing was the phrase “control system for controlling aseptic bottling conditions”, contained in several claims of U.S. Patent No. 6,536,188 (10-781, [318-3], pp. 29-30 (CM/ECF pagination)). Judge Connolly rejected Shibuya’s argument that this language constituted a means-plus-function claim, reasoning that “it’s not defined in [terms of]

² 35 U.S.C. §112(f) (formerly labeled §112(6)) provides that “[a]n element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof”.

functionality, because everybody in the field knows . . . what a control system means". [391-1], p. 87 (CM/ECF pagination). "I don't think [Shibuya] rebutted the presumption. The word means is not used. I think they're really making indefiniteness arguments and so I don't think it's a means-plus-function term. I'm not going to construe it." Id., p. 91.³

With due respect to Judge Connolly, this court is "not . . . bound by a claim construction adopted in another district court". Sprint Communications Co., L.P. v. Charter Communications, Inc., 2019 WL 1082067, *3 (D. Del. 2019). Not only is the claim language at issue here ("feedback control system") different from that addressed by Judge Connolly ("control system"), but whether one skilled in the art would understand the meaning of the claim language in the abstract does not end the court's inquiry. "In making the assessment of whether the limitation in question is a means-plus-function term . . . the essential inquiry is not merely the presence or absence of the word 'means' but whether the words of the claim are understood by persons of ordinary skill in the art to have a sufficiently definite meaning as the name for *structure*." Williamson, 792 F.3d at 1348 (emphasis added). "The inquiry is whether one of skill in the art would understand the specification *itself* to disclose a structure, not simply whether that person would be capable of implementing a structure." Biomedino, LLC v. Waters Technologies Corp., 490 F.3d 946, 953 (Fed. Cir. 2007) (emphasis added).

According to Steuben, the "function" described in Claim 9 is "maintaining aseptic bottling conditions", and the "structure" which performs that function is "a control system, and equivalents". Joint Claim Construction and Prehearing Statement [220], p. 13. However, "the reference to 'control' is simply an adjective . . . it is not a structure or material capable of

³ However, he noted that Shibuya "may have some serious indefiniteness arguments here because it seems to me there's a lot of room for interpretation as to what is needed". Id., pp. 91-92.

performing the identified function”, Biomedino, 490 F.3d at 950, and a “system is not a structure”. 3D Systems, Inc. v. Envisiontec, Inc., 2008 WL 324095, *4 (E.D. Mich. 2008).

While Steuben relies upon the testimony of Dr. Cullen Buie, who opines that “[t]he term ‘feedback control system’ connotes definite structure to a skilled artisan” (Second Buie Declaration, 10-cv-781, [334-6], ¶10),⁴ “[t]he testimony of one of ordinary skill in the art cannot supplant the total absence of structure from the specification The prohibition against using expert testimony to create structure where none otherwise exists is a direct consequence of the requirement that the specification adequately disclose corresponding structure”. Williamson, 792 F.3d at 1354; Noah Systems, Inc. v. Intuit Inc., 675 F.3d 1302, 1312 (Fed. Cir. 2012). Therefore, “a party advocating that a claim limitation that does not recite the word ‘means’ is subject to §112, para. 6 can overcome the presumption against its application solely by reference to evidence intrinsic to the patent”. Diebold Nixdorf, Inc. v. International Trade Commission, 899 F.3d 1291, 1299-1300 (Fed. Cir. 2018).

Not only does the patent specification fail to depict a structure for a “feedback control system”, it does not even *mention* that phrase. Although the specification describes “control and monitoring devices” (including a “bottle counter” (col. 14, l. 19) and numerous “sensors” (col. 14, l. 23 - col. 15, l. 29)), Steuben admits that “the feedback control system is [a] *separate* structure from the ‘control and monitoring devices’ that interface with it Those skilled in the art would understand that it is the feedback control system itself - not the monitoring devices - that actually ‘maintain[s]’ bottling conditions”. Steuben’s Markman Brief

⁴ This opinion is disputed by Kenneth R. Swartzel, Ph.D., who states that “[t]he ‘feedback control system’ term, as it appears in the claims, does not connote a definite structure. Instead, the claim simply recites that the ‘feedback control system’ can perform the function of maintaining aseptic bottling conditions”. Swartzel Declaration, 10-cv-781 [346-9], ¶13.

in Reply, 10-cv-781 [333], p. 41 (emphasis added); Asyst Technologies, Inc. v. Empak, Inc., 268 F.3d 1364, 1371 (Fed. Cir. 2001) (“[t]he corresponding structure to a function set forth in a means-plus-function limitation must actually perform the recited function, not merely enable the pertinent structure to operate as intended”).

The specification’s only depiction of the structure of a “control system” (not “*feedback control system*”) is a box entitled “Control System 550”, depicted in Figures 1, 3, 13 and 16. However, that depiction does not sufficiently describe a structure. *See Verint Systems Inc. v. Red Box Recorders Ltd.*, 166 F. Supp. 3d 364, 381 (S.D.N.Y. 2016) (“nor does the description of the ‘monitoring system’ in the specification point to a sufficiently definite structure to save [the] claim . . . from being construed as MPF [means-plus-function]. Figure 4 of the specification shows the ‘monitoring system’ as a box”); Williamson, 792 F.3d at 1350 (“the word ‘module’ does not provide any indication of structure because it sets forth the same black box recitation of structure for providing the same specified function as if the term ‘means’ had been used”); Blackboard, Inc. v. Desire2Learn, Inc., 574 F.3d 1371, 1382, 1383 (Fed. Cir. 2009) (“what the patent calls the ‘access control manager’ is simply an abstraction that describes the function of controlling access to course materials, which is performed by some undefined component of the system. The ACM is essentially a black box that performs a recited function. But how it does so is left undisclosed”); Biomedino, 490 F.3d at 949 (“[t]he only references in the specification to the ‘control means’ are a box labeled ‘Control’ in Figure 6 The fact that one skilled in the art could envision various types of equipment capable of automatically operating valves does not change the fact that no structure capable of performing that function was disclosed by the inventor”).

“The point of the requirement that the patentee disclose particular structure in the specification and that the scope of the patent claims be limited to that structure and its equivalents is to avoid pure functional claiming Without so limiting a claim . . . the patentee has not paid the price but is attempting to claim in functional terms unbounded by any reference to structure in the specification.” Blackboard, 574 F.3d at 1383.

“[T]he indefiniteness issue in this case is intertwined with claim construction.” Media Rights Technologies, Inc. v. Capital One Financial Corp., 800 F.3d 1366, 1371 (Fed. Cir. 2015). “If the patentee fails to disclose adequate corresponding structure, the claim is indefinite.” Williamson, 792 F.3d at 1352; Blackboard, 574 F.3d at 1382. Because the ‘013 patent fails to adequately identify a corresponding structure for Claim 9’s “feedback control system”, this court should conclude that Claim 9 is indefinite.⁵

B. “Disinfecting the Bottles . . . With Hot Hydrogen Peroxide Spray”.

Claim 20 of the ‘013 patent calls for “disinfecting the bottles . . . with hot hydrogen peroxide spray”. While Steuben initially suggested that this language needs no construction (Joint Claim Construction and Prehearing Statement [220], p. 11), it now contends that “a skilled artisan would understand that the ‘hot’ hydrogen peroxide refers to a sterilant temperature range that is hot enough to be effective, but not so hot as to deform the packaging material”. Declaration of Andre Sharon, Ph.D. (10-cv-781, [333-1]), ¶34.

However, Dr. Sharon cautioned that “the word that is used is hot, so it needs to be hot, not just effective”. Sharon deposition (10-cv-781 [346-3]), p. 54. His statement that “[h]ot means hot” (*id.*, p. 13) is not a meaningful description of the word. “[A] patent does not satisfy

⁵ In view of this ruling, I need not address defendants’ alternative arguments.

the definiteness requirement of § 112 merely because “a court can ascribe *some* meaning to a patent’s claims.” Interval Licensing LLC v. AOL, Inc., 766 F.3d 1364, 1371 (Fed. Cir. 2014) (emphasis in original). “The claims, when read in light of the specification and the prosecution history, must provide objective boundaries for those of skill in the art Even if a claim term’s definition can be reduced to words, the claim is still indefinite if a person of ordinary skill in the art cannot translate the definition into meaningfully precise claim scope.” Id.

Oystar and Jasper argue that this phrase is indefinite because there are no reasonably ascertainable parameters for what constitutes “hot” hydrogen peroxide spray. *See* Letter Briefs [387, 389, 393]. However, GEA suggested that the phrase be construed to mean that “[t]he hydrogen peroxide must be heated to its vaporization phase and applied to the bottles in [its] vaporization phase” (Joint Claim Construction and Prehearing Statement [220], pp. 11-12) and Jasper originally shared that view. Id.

As detailed by Nestle, “Steuben told the PTO that vaporizing the sterilant is critical to its invention”. Nestle’s Responding Markman Submission, 13-cv-892 [272], pp. 28-29. Therefore, a person skilled in the art “would understand this term . . . in the context of the specification and prosecution history of the ’013 patent to mean ‘a flow of hydrogen peroxide heated above its vaporization point’”. Declaration of Keith A. Ito, 13-cv-892, [272-71], ¶60. “[T]he patent, prosecution history, and testimony from Mr. Taggart all teach away from anything other than applying a vaporized sterilant to the bottles. It is my opinion, therefore, that a POSITA would understand the term ‘the disinfecting the bottles is with hot hydrogen peroxide spray’ means ‘a flow of hydrogen peroxide heated above its vaporization point’”. Declaration of Bruce A. Cords, Ph.D., 12-cv-904 [426-72], ¶71.

Steuben now suggests that although it “maintains that ‘hot hydrogen peroxide spray’ includes, but is not limited to, a vapor . . . and needs no construction, it does appear that if Your Honor were to limit claim 20 to requiring that the hydrogen peroxide be heated to its vaporization point prior to application to the bottle, such a finding would resolve the claim construction issue to the extent necessary in this proceeding”. Steuben’s Letter Brief [388], p. 11. However, it “disagree[s] with Defendants’ further suggestion that the hydrogen peroxide must be applied to the bottles in its vaporization phase. While the claim would include embodiments where the hot hydrogen peroxide spray is applied to the bottle in its vaporization phase, it would be improper to impose such a requirement on the claim because doing so would exclude a preferred embodiment More specifically, in a preferred embodiment, the patent explains that the hydrogen peroxide is applied as a ‘fog’ or ‘heated vapor fog.’ [See Dkt. 238-4 at 6:5-24, 8:14-44]. The patent’s disclosure in that regard makes sense to the POSITA because once the hydrogen peroxide is heated to its vaporization phase, it will cool when mixed with air downstream of the vaporization element (*e.g.*, in the pipes, inside the sterilization tunnel, inside the bottle). In the preferred embodiment, when that mixing occurs, the hydrogen peroxide vapor will condense forming a fog.” Id.

Accordingly, I recommend that this court construe the phrase “disinfecting the bottles . . . with hot hydrogen peroxide spray” to mean that the hydrogen peroxide must be heated to its vaporization phase immediately before being applied to the container. While the word “immediately” is itself somewhat imprecise, “the definiteness requirement must take into account the inherent limitations of language Some modicum of uncertainty . . . is the price of ensuring the appropriate incentives for innovation”. Nautilus, Inc. v. Biosig Instruments, Inc., 572 U.S. 898, 909 (2014). Therefore, the patent “need not define [the] invention with

mathematical precision”, but need only “provide enough certainty to one of skill in the art when read in the context of the invention”. Sonix Technology Co. v. Publications International, Ltd., 844 F.3d 1370, 1377 (Fed. Cir. 2017).

C. Claim 20: “Wherein a Residual Level of Hydrogen Peroxide is less than 0.5 PPM”.

Steuben contends that no construction of this phrase is necessary. Joint Claim Construction and Prehearing Statement [220], p. 17. The Oystar defendants argue that this phrase is indefinite because “there is no notice, much less clear notice, as to whether a residual amount of sterilant less than 0.5 PPM is required before, or after, filling and packaging” (Oystar Letter Brief [387], p. 5), and Jasper argues that it is indefinite “because it fails to provide reasonable clarity as to where or when this residual level is to be measured (e.g., in the bottling machine; the inside and/ or outside of the bottles after aseptic disinfecting but before filling; the inside and/or outside of the bottles after aseptic disinfecting and filling; the inside and/or outside of the bottles after aseptic disinfecting, filling and capping; on the lids; in the environment outside of the bottling machine)”. Joint Claim Construction and Prehearing Statement [220], p. 17.

It is not seriously disputed that the phrase at issue refers to 21 C.F.R. §178.1005(d), the FDA’s regulation governing the use of hydrogen peroxide in the sterilization of food packaging material. *See, e.g.*, Declaration of Sudhir K. Sastry, Ph.D., 12-cv-904, [466-1], ¶27; PTAB Final Written Decision on Remand, 12-cv-904, [568-1], pp. 47-48; Declaration of Keith A. Ito, 13-cv-892, [272-71], ¶30; Nestle USA, Inc. v. Steuben Foods, Inc., 686 Fed. App’x 917, 919 (Fed. Cir. 2017) (“the FDA’s hydrogen peroxide residue standard applies to *all* foodstuffs, regardless of whether they are aseptically packaged”) (emphasis in original); Judge Connolly’s comments, [391-1], p. 17 (CM/ECF pagination) (“these patents have claims that

expressly require less than .5 ppm of hydrogen peroxide residue as Section 178.1005(d) requires”).

Section 178.1005(d) defines how, when and where the hydrogen peroxide residue level is determined: “[n]o use of hydrogen peroxide solution in the sterilization of food packaging material shall be considered to be in compliance if more than 0.5 part per million of hydrogen peroxide can be determined in *distilled water packaged* under production conditions (assay to be performed immediately *after packaging*)” (emphasis added). In context, then, the “assay”⁶ is performed immediately after packaging of the distilled water in the container, rather than of the foodstuffs which are subsequently packaged therein. *See United States v. Atilla*, 966 F.3d 118, 126 (2d Cir. 2020) (“courts are generally averse to giving the same words different meanings when construing . . . regulations”). As Steuben argued at the Markman hearing, “the residue is dried. And so to take the measure of that you need to fill it with water.” [386], p. 55.

Therefore, the as used in Claim 20 of the ‘013 patent, the “residual level of hydrogen peroxide” means the level determined in accordance with 21 C.F.R. §178.1005(d).

CONCLUSION

For these reasons, I recommend that the court adopt the constructions discussed herein. Unless otherwise ordered by District Judge Elizabeth Wolford, any objections to this Report and Recommendation must be filed with the clerk of this court by September 17, 2020 . Any requests for extension of this deadline must be made to Judge Wolford. A party who “fails

⁶ An “assay” is an “examination and determination as to characteristics (such as weight, measure, or quality)”. Merriam-Webster Unabridged Online Dictionary.

to object timely . . . waives any right to further judicial review of [this] decision". Wesolek v. Canadair Ltd., 838 F. 2d 55, 58 (2d Cir. 1988); Thomas v. Arn, 474 U.S. 140, 155 (1985).

Moreover, the district judge will ordinarily refuse to consider *de novo* arguments, case law and/or evidentiary material which could have been, but were not, presented to the magistrate judge in the first instance. Patterson-Leitch Co. v. Massachusetts Municipal Wholesale Electric Co., 840 F. 2d 985, 990-91 (1st Cir. 1988). The parties are reminded that, pursuant to Rule 72(b) and (c) of this Court's Local Rules of Civil Procedure, written objections shall "specifically identify the portions of the proposed findings and recommendations to which objection is made and the basis for each objection . . . supported by legal authority", and must include "a written statement either certifying that the objections do not raise new legal/factual arguments, or identifying the new arguments and explaining why they were not raised to the Magistrate Judge". Failure to comply with these provisions may result in the district judge's refusal to consider the objections.

Dated: September 3, 2020

/s/ Jeremiah J. McCarthy
JEREMIAH J. MCCARTHY
United States Magistrate Judge